Attachment 1
Summary of Safety and Effectiveness

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h)

General Information:

MAR 13 2008

Trade Name:	NeuViz Spiral CT Scanner System
Common Name:	CT Scanner
Classification Name:	21 CFR Part 892.1750 Computed Tomography X-ray System
Classification:	Class II
Performance Standard:	21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard
Manufacture:	PHILIPS AND NEUSOFT MEDICAL SYSTEMS CO., LTD. Neusoft Park, Hun Nan Industrial Area, Shenyang 110179, P.R.China
Distributor:	NEUSOFT MEDICAL SYSTEMS CO., LTD. No.3-11,Wenhua Road, Heping District, Shenyang, P.R.China Post Code : 110004
Submitter:	Contact : Tianyanfang Title : Manager of Q&R Department Tel : 86-24-83660649 Fax : 86-24-83780480 E-Mail : Tianyanfang@neusoft.com

Summary prepared :Dec. 28, 2007

Safety and Effectiveness information

Intended Uses:

The NeuViz Spiral CT Scanner System is intended to produce cross-section images of head and whole body by computer reconstruction of X-ray transmission data taken at different angles.

Device Description:

The NeuViz Spiral CT Scanner System is composed of a gantry, a patient couch, an operator console and includes image acquisition hardware and software, and associated accessories. It is designed to be a head and whole body X-ray computed tomography scanner which features a continuously rotating tube-detector system and functions according to the fan beam principle. The system software is an interactive program used for X-ray scan control, image reconstruction, and image archive/evaluation.

The NeuViz Spiral CT Scanner System uses the same materials, construction and operating principle as our existing marketed product, NeuViz Dual Multi-slice CT Scanner System.

Predicated Device:

NeuViz Dual Multi-slice CT Scanner System (K071308)

Statement of Substantial Equivalence:

The NeuViz Spiral CT Scanner System is of comparable type and substantially equivalent to the NeuViz Dual Multi-slice CT Scanner System (K071308) that complies with the same or equivalent standards and has the same intended uses. Both of these systems use on-board high frequency High-Voltage generator to generate X-radiation from X-ray tube. The X-ray transmission data is detected by the solid-state detector and is reconstructed by the computer which has an interactive user interface. Both of these devices produce two dimensional image and 3D image that can be filmed or electronically stored for future review.

a. Non-clinical tests: The device has been evaluated for performance, biocompatibility and effectiveness as well as electdical ,mechanical, chemical, biological, and radiation safety and has been found to substantially equivalent to predicate device. The design and development process of the manufacturer conforms to 21 CFR part 820, ISO 9001 and ISO 13485 quality systems.
b. Clinical tests: No clinical tests conducted.
c. Conclusion: The device was evaluated against the predicate device (NeuViz Dual Multi-slice CT Scanner System (K071308)) for all performance, safety & effectiveness requirements and found as substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 13 2008

Neusoft Medical Systems Co., Inc.
c/o TUV Rheinland of North America
12 Commerce Rd.
Newton, CT 06470

Re: K080540
Trade/Device Name: Neusoft Spiral CT Scanner System (Modified) V2.0 (Model NeuViz)
Regulation Number: 21 CFR 1750
Regulation Name: Computed tomography x-ray system
Regulatory Class:. Class II
Product Code: JAK
Dated: February 25, 2008
Received: February 27, 2008

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 2
Indications for Use Statement

510(k) Number: K080540

Device Name: NeuViz Spiral CT Scanner System

Environment of Use / Patient Population:

The NeuViz Spiral CT Scanner Systems are intended to produce cross-section images of head and whole body by computer reconstruction of X-ray transmission data taken at different angles.

Prescription Use: YES
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use: NO
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF DEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080540